STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

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Effects of a Standardized Walking Program in a High-Quality Natural Tourism Environment on Health Outcomes in Sedentary, Overweight Older Women: A 10-Week Randomized Controlled Trial

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1. ABSTRACT

Background: Built and natural environments are recognized as key determinants of health behaviors and outcomes. Sedentary, overweight older women face heightened risks of physical and psychological decline. This study examines whether conducting a standardized walking program within a high-quality tourism environment yields greater health benefits than the same program in a conventional setting.

Methods: In this 10-week randomized controlled trial, 50 eligible women (age ≥ 60 years, BMI ≥ 24.0 kg/m²) are assigned to either an experimental group (NCE, n = 25) that exercises in Yangshuo's iconic karst landscape, or an active control group (CCE, n = 25) that performs the identical supervised walking regimen in a nursing home setting. The program consists of group walking sessions (5 days/week, 60 mins/session) at a target intensity of 60-70% heart rate reserve, with exercise intensity objectively monitored. Physiological, psychological, and behavioral outcomes are assessed at baseline and post-intervention.

Conclusion: This trial will determine whether a high-quality natural environment can selectively enhance certain health outcomes within a standardized exercise program for older women.

2. INTRODUCTION

2.1 Background and Rationale

The 21st century is marked by a profound demographic transition toward aging populations worldwide, a shift that has significant public health and economic implications. Older women are particularly vulnerable, as they face a high prevalence of overweight and obesity. This excess adiposity is not simply cosmetic; it can accelerate muscle loss (sarcopenia); impair mobility; elevate the risk of chronic conditions, such as diabetes and hypertension; and ultimately erode independence and quality of life. Further, the psychological well-being of this group is often threatened by increased risks of depression, anxiety, and social isolation, creating a complex interplay of physical and mental health decline.

Within this challenging landscape, physical exercise is well-established as an effective non-pharmacological intervention. Research confirms that structured programs, particularly those that blend resistance training with aerobic activity, are highly effective at mitigating age-related decline. Meta-analyses consistently affirm benefits spanning improved body composition, enhanced muscular strength and functional capacity, and reduced symptoms of depression and anxiety. Consequently, regular physical activity is universally recommended as an important component of healthy aging.

A growing body of evidence specifically highlights the unique value of outdoor physical activity, such as walking, hiking, and other forms of exercise conducted in natural settings, beyond the benefits of indoor exercise. While adherence to any exercise is beneficial, exercising outdoors has been linked to distinct advantages that cannot be fully replicated indoors, such as higher levels of enjoyment, greater feelings of revitalization, and increased positive affect during and after the activity. These enhanced psychological responses are important, as enjoyment is a key predictor of long-term exercise adherence. Furthermore, variable terrain, changing scenery, and exposure to

fresh air and natural light inherent in an outdoor exercise like walking can provide richer sensory stimulation, potentially leading to superior cognitive engagement and mood regulation. Importantly, for populations such as older adults, outdoor walking is a highly accessible, low-impact activity that supports both cardiovascular health and functional mobility.

Despite this recognition, a critical and under-investigated gap persists in the literature. The benefits of outdoor exercise are often presented generically, with insufficient attention paid to the specific quality and characteristics of the natural environment itself. Not all "outdoor" or "natural" settings are equal. Thus, a key question emerges: does conducting the same exercise prescription, with identical frequency, intensity, time, and type (FITT principles), in a visually stunning, restorative natural environment yield greater health benefits than when conducted in a bland, confined, or less inspiring outdoor setting? Current research has predominantly focused on comparing indoor versus outdoor exercise broadly, or on the presence versus absence of "green space". This oversight neglects the potential for environmental aesthetics and restorative quality to function as an active therapeutic ingredient that amplifies the effects of physical activity.

2.2 Theoretical Framework

The notion that the environment itself can serve as an active therapeutic agent is strongly supported by theoretical frameworks that directly link environmental quality to well-being. Kaplan's attention restoration theory (ART) provides a compelling explanation. It posits that natural environments that offer a sense of "being away" (psychological distance from routine demands), "fascination" (effortlessly capturing attention through aesthetic appeal), "extent" (a coherent, immersive setting), and "compatibility" (alignment between environmental features and an individual's purposes) are uniquely capable of restoring depleted cognitive and emotional resources.

Similarly, Ulrich's stress reduction theory (SRT) proposes that exposure to aesthetically pleasing natural scenes can trigger rapid, unconscious psychophysiological changes that promote stress reduction, positive emotional states, and physiological relaxation. These theories suggest that a high-quality natural environment does more than provide a venue for exercise; it interacts with the individual to enhance the restorative and motivational processes during the activity.

Building on this, we posit that for structured health interventions, the defining environmental factor is not simple outdoor access, but rather the rich, multisensory, restorative, and awe-inspiring experience offered by a premier natural tourism destination. Characterized by their extraordinary scenic beauty, cultural significance, and immersive qualities, such environments represent the pinnacle of a restorative environment. They provide an ideal setting to test the hypothesis that environmental quality can amplify the physical and mental health benefits derived from a standardized exercise protocol.

2.3 Study Setting: Yangshuo, China

Yangshuo, China, a UNESCO World Heritage site, serves as our paradigm of such a high-quality

environment. Its iconic landscape of towering karst limestone peaks rising from tranquil rivers and lush countryside is not merely a visual backdrop. For an older adult engaging in prescribed walking sessions here, the environment actively contributes to the intervention. The awe-inspiring scenery induces the "fascination" central to ART, while the physical displacement to a tourist destination creates a sense of "being away" from daily routines and institutional confines. This can lower psychological barriers to adopting a new exercise regimen. The natural beauty acts as a potent positive distraction, making the perception of physical effort more manageable and transforming exercise from a chore into an engaging, enjoyable experience. Moreover, such a setting fosters a unique social atmosphere—a liminal space outside of normal life—that can naturally encourage social interaction, strengthen group cohesion, and combat feelings of loneliness, which are prevalent among older adults.

Therefore, we conceptualize the high-quality tourism environment of Yangshuo not as a passive setting, but rather as an integral, active component of the therapeutic intervention, one that works synergistically with the physiological stimulus of exercise.

3. OBJECTIVES AND HYPOTHESES

3.1 Primary Objective

To determine whether conducting a standardized 10-week supervised walking program in a high-quality natural tourism environment (Yangshuo) leads to superior improvements in body composition (body fat percentage, body weight, BMI) and muscular strength (lower-body endurance and handgrip strength) compared to the same program conducted in a conventional institutional setting (nursing home).

3.2 Secondary Objectives

To determine whether the high-quality natural tourism environment leads to superior improvements in:
- Depressive symptoms
- State anxiety
- Mental health-related quality of life
- Sleep quality
- Perceived personal mastery

3.3 Hypotheses

H1: Environmental Synergy Hypothesis for Physiological Gains: The group exercising in Yangshuo (natural commercial environment, NCE) will achieve significantly greater reductions in body fat percentage (H1a), body weight (H1b), and BMI (H1c), and greater improvements in lower-body muscular strength (H1d) and handgrip strength (H1e) than the control group in the conventional setting (conventional control environment, CCE).
H2: Environmental Facilitation Hypothesis for Psychological Restoration: The NCE group will

demonstrate significantly larger reductions in depressive (H2a) and anxiety (H2b) symptoms, and a significantly greater increase in mental health-related quality of life (H2c) than the CCE group.
H3: Environmental Empowerment Hypothesis for Cognitive-Behavioral Outcomes: The NCE group will show significantly greater improvements in sleep quality (H3a) and perceived personal mastery (H3b) than the CCE group.
It is hypothesized that a significant Time × Group interaction will be observed for all outcome measures, confirming that the superior environmental context of Yangshuo amplifies the benefits derived from the standardized exercise protocol.

4. STUDY DESIGN

This investigation is a 10-week, two-arm, parallel-group randomized controlled trial to rigorously evaluate the differential effects of environmental context on the outcomes of a standardized exercise program.

Study Timeline:
- Participant recruitment: May 1, 2024 – June 30, 2024
- Intervention period: July 1, 2024 – September 8, 2024
- Post-intervention assessments: September 9, 2024 – September 15, 2024
- Data analysis: September 2024 – December 2024

Study Flow:
1. Recruitment and screening
2. Information session and informed consent
3. Baseline assessments (T0)
4. Randomization
5. Intervention period (10 weeks)
    - NCE group: Walking in Yangshuo environment
    - CCE group: Walking in nursing home environment
6. Post-intervention assessments (T1)
7. Data analysis

Randomization:
Eligible participants will be randomly allocated to one of the two study groups using a computer-generated sequence prepared by an independent researcher not involved in recruitment or assessment, thereby ensuring robust randomization. Allocation concealment will be maintained until after baseline assessments are completed.

Blinding:
The researchers responsible for conducting all outcome assessments at baseline and post-intervention will be blinded to the participants' group allocation (NCE or CCE) throughout the entire study period. Participants and exercise coaches cannot be blinded due to the nature of the environmental intervention.

5. PARTICIPANTS

5.1 Target Population

Community-dwelling sedentary, overweight older women in the Guilin, China area.

5.2 Sample Size Calculation

Sample size was determined a priori using G*Power 3.1 software. Based on previous research examining environmental effects on exercise outcomes, a medium effect size ($f^2 = 0.25$) was assumed. For a 2 (group) × 2 (time) repeated-measures ANOVA, with power ($1 – \beta$) set at 0.80 and $\alpha = 0.05$, the calculation indicated that at least 22 participants per group were required to detect a significant interaction. Accounting for an estimated 10% attrition rate, a total of 50 participants (25 per group) will be recruited.

5.3 Eligibility Criteria

Inclusion Criteria:

- Female sex
- Age ≥ 60 years
- Body mass index (BMI) ≥ 24.0 kg/m² (consistent with Chinese criteria for overweight status)
- Sedentary lifestyle, defined as engaging in < 60 minutes of moderate-intensity exercise per week over the preceding 6 months
- Ability to walk independently without assistive devices
- Sufficient cognitive capacity to understand the study protocol and provide written informed consent

Exclusion Criteria:

- Severe or uncontrolled cardiometabolic conditions (e.g., heart failure, unstable angina)
- Musculoskeletal disorders contraindicating exercise
- Major psychiatric disorders
- Planned extended absence during the 10-week intervention period

5.4 Recruitment

Participants will be recruited from the Guilin, China area through targeted local advertisements and community outreach. Recruitment materials will include flyers posted in community centers, senior activity centers, and local clinics, as well as word-of-mouth referrals.

5.5 Informed Consent Process

Prior to randomization and baseline assessment, all eligible participants will attend a dedicated information session. During this session, the research team will thoroughly explain the study's purpose, procedures, potential benefits, and foreseeable risks. The time commitment and expectations for the 10-week intervention will be clarified. It will be explicitly emphasized that participation is entirely voluntary and that participants reserve the right to withdraw from the study at any point without penalty or detriment to their future care. Following this comprehensive discussion and after all questions have been answered, individuals who voluntarily agree to participate will provide written informed consent.

6. INTERVENTIONS

6.1 Overview

The core exercise intervention is identical for both groups, consisting of a supervised program conducted 5 days per week over a 10-week period. Participants must attend at least four sessions per week to be considered compliant with the protocol. The key differentiator between the groups is the environmental context in which this program is delivered.

6.2 Experimental Group (NCE)

Setting: Participants in the NCE group will be accommodated in a carefully curated homestay located within 200 meters of the scenic Yulong River area in Yangshuo, renowned for its breathtaking karst topography. The homestay rooms are specifically selected to provide direct, unobstructed views of the iconic karst mountains.

Walking Route: Outdoor walking sessions will be conducted on pre-selected, scenic, and low-traffic riverside paths.

6.3 Active Comparator Group (CCE)

Setting: Participants in the CCE group will continue to reside in their usual accommodation within a local nursing home facility. The views from their rooms encompass other institutional buildings or internal courtyards.

Walking Route: Outdoor walking sessions will occur on pre-measured, paved urban streets surrounding the nursing home, characterized by typical urban sights and sounds.

6.4 Exercise Protocol

The exercise regimen is standardized and supervised by certified fitness professionals to ensure consistency and safety. The aerobic component for both groups consists of a supervised walking program, designed to be matched as closely as possible on all key objective training parameters, with the environmental context serving as the primary intended difference between groups.

Parameter	Specification
Frequency	5 sessions per week
Session Duration	60 minutes
Intensity	60-70% of heart rate reserve (HRR)
Mode	Group walking
Duration	10 weeks

6.5 Quality Assurance and Monitoring

To maximize internal validity, all exercise sessions for both groups will be delivered by the same team of certified exercise coaches, who will adhere to a detailed, standardized protocol manual.

Exercise Intensity Monitoring: To standardize the dose of exercise and minimize inter-group

differences in exertion, real-time exercise intensity will be objectively monitored for every participant using Polar H10 chest-worn heart rate sensors. Coaches will use this live feedback to provide individual guidance, aiming to ensure participants in both groups exercise within the same target heart rate zone.

Adherence Monitoring: Attendance at all scheduled sessions will be recorded. Participants attending less than 80% of sessions (i.e., < 40 out of 50 sessions) will be considered non-compliant but will be included in intention-to-treat analysis.

6.6 Concomitant Care

Participants in both groups will be instructed to maintain their usual dietary habits and not to initiate any new exercise programs outside of the study intervention during the 10-week period.

7. OUTCOME MEASURES

A comprehensive battery of assessments will be administered to all participants at two time points: prior to the initiation of the intervention at baseline (T0), and within one week following the completion of the 10-week intervention (T1).

7.1 Primary Outcome Measures

Measure	**Instrument/Test**	**Description**	**Unit/Score Range**
Body fat percentage	InBody 770 (multi-frequency BIA)	Measured under standardized conditions	%
Body weight	InBody 770	Measured under standardized conditions	kg
Body mass index (BMI)	Calculated from weight and height	Weight (kg) / Height (m^2)	kg/m^2
Lower-body muscular endurance	30-second chair stand test	Number of full stands from a seated position in 30 seconds	number of stands
Upper-body muscular strength	Handgrip dynamometer	Maximum grip strength of dominant hand	kg

Standardized Measurement Conditions for BIA:

- Refrain from strenuous exercise for 24 hours
- Avoid alcohol and caffeine consumption for 12 hours
- Maintain normal fluid intake while avoiding excessive water consumption within 2 hours of testing
- Empty bladder 30 minutes prior to measurement
- All follow-up assessments scheduled at the same time of day (±2 hours) as baseline

7.2 Secondary Outcome Measures

Construct	Instrument	Description	Score Range
Depressive symptoms	Center for Epidemiologic Studies Depression Scale (CES-D)	20-item scale assessing frequency of depressive symptoms in past week	0-60 (higher = worse)
State anxiety	State-Trait Anxiety Inventory - State subscale (STAI-S)	20-item scale measuring transient anxious emotional states	20-80 (higher = worse)
Mental health-related quality of life	SF-36 Mental Component Summary (MCS)	Aggregates dimensions of mental health, vitality, social functioning	Mean=50, SD=10 (higher = better)
Sleep quality	Pittsburgh Sleep Quality Index (PSQI)	19-item instrument assessing sleep quality over past month	0-21 (>5 = poor sleep)
Perceived mastery	Pearlin-Schooler Mastery Scale	7-item scale assessing perceived control over life forces	7-28 (higher = better)

Psychometric Properties:

Scale	Cronbach's α (current study)
CES-D	0.92
STAI-S	0.89
SF-36 MCS	[to be reported]
PSQI	0.78
Mastery Scale	0.85

7.3 Other Measures

Demographic and Baseline Characteristics:
- Age
- Educational level
- Marital status
- Living situation
- Medical history
- Medication use

Adherence and Safety:
- Session attendance rate
- Adverse events (type, severity, relation to intervention)

8. STATISTICAL ANALYSIS PLAN

8.1 General Principles

All statistical analyses will be performed using IBM SPSS Statistics software, Version 26.0. A two-tailed p-value of less than 0.05 will be chosen as the threshold for statistical significance for all tests. Effect sizes will be reported using partial eta-squared (η^2) for ANOVA models.

8.2 Data Screening and Preparation

- Normality: The normality of the distribution of all continuous outcome variables will be verified using the Shapiro-Wilk test and visual inspection of Q-Q plots.
- Outliers: Extreme outliers (≥ 3 SD from mean) will be winsorized or, if clearly erroneous, removed.
- Missing Data: Patterns of missing data will be examined. If data are missing completely at random (MCAR), complete-case analysis will be performed. If missing data are related to observed variables, multiple imputation will be considered.

8.3 Primary Analysis

The primary analysis for each outcome measure will consist of a 2 (Time: T0, T1) × 2 (Group: NCE, CCE) repeated-measures analysis of variance (ANOVA). In this model:

- Main effect of Time: Indicates whether outcomes change significantly from baseline to post-intervention across both groups.
- Main effect of Group: Indicates whether there are overall differences between groups regardless of time.
- Time × Group interaction effect: Indicates whether the change over time differs significantly between the two environments. This is the primary effect of interest for testing study hypotheses.

If a significant interaction is detected, simple effects analyses will be conducted to probe the nature of the interaction further, examining:

- Within-group changes over time (paired t-tests or Wilcoxon signed-rank tests)
- Between-group differences at each time point (independent t-tests or Mann-Whitney U tests)

8.4 Analysis Populations

- Intention-to-Treat (ITT): All randomized participants will be included in the primary analysis, regardless of adherence, analyzed according to their original group assignment.
- Per-Protocol (PP): A secondary analysis will be conducted including only participants who completed at least 80% of scheduled sessions. Results from ITT and PP analyses will be compared.

8.5 Subgroup Analyses

If sample size permits, exploratory subgroup analyses may be conducted based on:

- Baseline BMI category (overweight vs. obese)
- Baseline depression status (CES-D ≥ 16 vs. < 16)

These analyses are exploratory and will be interpreted cautiously.

8.6 Handling of Covariates

Baseline characteristics that differ between groups despite randomization ($p < 0.10$) will be

considered as covariates in ANCOVA models to adjust for potential confounding.

8.7 Statistical Power

Based on the sample size calculation, the study is adequately powered (80%) to detect a medium effect size ($f^2 = 0.25$) for the Group × Time interaction in repeated-measures ANOVA.

9. ETHICAL CONSIDERATIONS

9.1 Ethical Approval

The study protocol received full ethical approval from the Institutional Review Board of Guilin Tourism University scientific research (2024) No. 27. Any protocol amendments will be submitted for ethical review and approval prior to implementation.

9.2 Declaration of Helsinki

This study will be conducted in strict accordance with the ethical principles outlined in the Declaration of Helsinki.

9.3 Informed Consent

Written informed consent will be obtained from all participants prior to any study procedures. The consent form will include:

- Purpose of the study
- Study procedures and duration
- Potential risks and benefits
- Confidentiality assurances
- Voluntary participation and right to withdraw
- Contact information for questions

9.4 Risks and Benefits

Potential Risks:

- Musculoskeletal injury during exercise (minimized by supervised sessions, warm-up/cool-down, and progression monitoring)
- Fatigue or discomfort (participants can rest as needed)
- Minor skin irritation from heart rate monitor straps

Potential Benefits:

- Improved physical fitness and body composition
- Enhanced psychological well-being
- Social interaction and support

9.5 Risk Mitigation

- All sessions supervised by certified exercise professionals
- Emergency procedures in place at both locations
- Pre-exercise health screening
- Continuous monitoring of participant well-being
- Clear stopping criteria for adverse events

9.6 Withdrawal Criteria

Participants may be withdrawn from the study for:

- Voluntary withdrawal at any time
- Serious adverse event related to the intervention
- Development of exclusion criteria during the study
- Non-compliance (attendance < 40% despite encouragement)

10. DATA MANAGEMENT AND CONFIDENTIALITY

10.1 Data Collection

All data will be collected using standardized case report forms (CRFs) and entered into a secure electronic database. Double data entry will be performed for a random 10% of cases to verify accuracy.

10.2 Data Storage and Security

- All paper documents will be stored in locked filing cabinets in a secure office
- Electronic data will be stored on password-protected computers with encrypted hard drives
- Backups will be maintained on secure university servers
- Access to data will be restricted to authorized study personnel only

10.3 Confidentiality

- Participants will be identified only by a unique study ID number on all data collection forms
- No participant names or identifying information will be included in any publication or presentation
- A master list linking participant names to IDs will be stored separately from data

10.4 Data Sharing

Individual participant data (IPD) will not be shared publicly due to ethical and privacy considerations. Although the data are de-identified, the combination of detailed demographic information (e.g., age, BMI, sedentary status) and specific environmental exposure (Yangshuo tourism setting) could potentially allow for the re-identification of participants in this small cohort study (N=50). Furthermore, the informed consent obtained from participants did not include provisions for public data sharing. De-identified and aggregated summary data supporting the findings of this study will be available from the corresponding author upon reasonable request.

11. DISSEMINATION POLICY

11.1 Publication Plan

Results of this study will be disseminated through:

- Peer-reviewed journal publications
- Presentations at scientific conferences
- Summary reports for participants
- ClinicalTrials.gov results submission

11.2 Authorship Criteria

Authorship on resulting publications will be determined according to the International Committee of Medical Journal Editors (ICMJE) guidelines: substantial contributions to conception/design, acquisition of data, or analysis/interpretation; drafting or revising the manuscript; final approval;

and agreement to be accountable for all aspects of the work.

11.3 ClinicalTrials.gov Registration

This study will be registered on ClinicalTrials.gov prior to participant enrollment. Results will be submitted to ClinicalTrials.gov within one year of study completion.

Informed Consent Form for Experiment

Dear Experimental Participant: Thank you for participating in our experimental project. Before you participate, please ensure that you have carefully read and understood the contents of the following informed consent form. This informed consent form will detail the purpose, process, potential risks, and your rights of the experiment.

Experimental Objective: This experiment aims to investigate the correlation between a tourist attraction and weight loss. Experimental Procedure: Before the experiment begins, we will provide you with detailed instructions and the experimental process. You will complete the assigned tasks at the designated location and cooperate with us in collecting data and making records.

Compensation and Risks: Expenses incurred for transportation, catering, etc. due to research needs can be reimbursed with receipts. This study has been approved by the ethics committee and carries low risks. If you experience any discomfort, please inform the researcher immediately, and we will take prompt measures to address it.

As a participant, you enjoy the following rights:

1. The right to independently decide whether to participate in the experiment and freely choose to withdraw from it.

2. Obtain a comprehensive and clear explanation of the experimental purpose, process, risks, and expected results.

3. The right to protect personal privacy and data.

4. Obtain feedback and summarize the experimental results.

Your data and privacy will be strictly protected and used solely for the purpose of this study. We will properly store and process the data in accordance with relevant laws and regulations. Please confirm your understanding and agreement to the above content by signing your name in block letters in the box below this page, indicating your informed consent and voluntary participation in this experiment.

If you have any questions about any part, please communicate with us before participating in the experiment. Thank you for your cooperation and support!

Yours sincerely!
